MISSOURI COMMISSION ON PATIENT SAFETY
MEETING MINUTES
November 19, 2003
10:00 a.m. – 4:00 p.m.
Missouri State Capitol Building
Jefferson City, Missouri

Official

Commissioners in attendance: Gregg Laiben, Kathryn Nelson, James Buchanan, Thomas Cartmell, Deborah Jantsch, Susan Kendig, Nancy Kimmel, Scott Lakin, Pamela Marshall, Alan Morris, Bea Roam, William Schoenhard, Stephen Smith, Barry Spoon, James Utley, Kenneth Vuylsteke, Tina Steinman, Lori Scheidt, and Kevin Kinkade.

I. CALL TO ORDER

Gregg Laiben, Chairperson
The meeting was called to order at 10:06 a.m. Silent roll call was taken. Dr. Laiben opened the meeting with the following housekeeping items:
Due to scheduling conflicts, it was announced that Gregg Laiben, Kathryn Nelson, Scott Lakin, and Dick Dunn would not be able to attend the proposed December 3rd meeting. The scheduled meeting for December 3rd was cancelled. The commission scheduled its next meeting for December 17th in the State Capitol building, House Hearing Room 1. There have been numerous requests to present to the commission. The agendas for the next three to four meetings are tentatively scheduled to bring in many presenters, with the commissioners' approval. This was approved by a verbal vote of the commission. Ms. Nelson reminded commissioners that if he or she becomes aware of any future requests to make a presentation, forward this information to Linda Bohrer. Dr. Laiben introduced Linda Bohrer.

Linda Bohrer, Division Director for Consumer Affairs, Missouri Department of Insurance
Addressed the following items:
There was a correction to the contact information for Dr. James Buchanan. His telephone number ends with a 7 (seven), not a 1 (one) as listed in the handbook. The Patient Safety Commission web site is now active. The address for the Patient Safety Commission web page is http://insurance.mo.gov/aboutMDI/issues/patsafety/index.htm.
Handouts for today's presentations were distributed at this time. The following PowerPoint handouts were distributed:

- Tim Anderson, Patient Safety Manager, Harry S. Truman Memorial Veterans Hospital
- Nancy Kimmel, Patient Safety Specialist, Missouri Baptist Medical Center

- Brent Kabler, Research Supervisor, Missouri Department of Insurance
- Lori Scheidt, Executive Director, Board of Nursing
- Lois Kollmeyer, Director, DHSS Section for Health Standard and Licensure

Tina Steinman of the Board of Healing Arts will provide information in a written format at a later date. The most recent Missouri Department of Insurance Medical Malpractice Report was distributed to commissioners and the public. The 2003 report contains data from the calendar year 2002. The "data dictionary" that was requested was supplied in the last meeting on the Claim Report Form.

Gregg Laiben, Chairperson
Asked commissioners to review the minutes of the previous meeting. Dr. Utely asked that a phrase on page four, "might be found", be deleted and replaced with "show". No other corrections were requested. Dr. Spoon motioned to approve the minutes. The commission approved the minutes by verbal vote.

II. HARRY S. TRUMAN MEMORIAL VETERANS HOSPITAL PRESENTATION

Tim Anderson, Patient Safety Manager, Harry S. Truman Veterans Hospital

Presented a PowerPoint on Root Cause Analysis. (Handouts of the presentation are available) Mr. Anderson made it clear before his presentation that he was not representing Dr. Jim Bagain. Additional handouts were distributed at this time. Kathryn Nelson noted that the Veterans Administration (VA) hospital system is a national leader in patient safety management, and that Mr. Anderson is an active leader himself, providing her with guidance on patient safety issues at the University Hospital.
The handouts that accompanied Mr. Anderson's presentation were:

- "Root Cause Analysis Overview and Definitions (The Big Picture)" (prints of slides)
- "Root Cause Analysis (RCA) Form"
- "Ensuring Correct Surgeries in the Veterans Health Administration"
- "Safety Assessment Code (SAC) Matrix"
- "Triage and Triggering Questions for Root Cause Analysis"
- "Using the Five Rules of Causation"
- "Mining for Gold – Patient Safety Nuggets"
- "Root Cause Analysis Tools Version: August 2002" (laminated flip chart)

Mr. Anderson supplied additional background information. He is a psychiatric nurse, and his presentation is a distillation of national VA office materials. The presentation provides general information on the Root Cause Analysis (RCA) process used throughout the VA system. RCA data from all over the country is aggregated with the national VA offices. The VA has this data for approximately the last four years.

Mr. Anderson strongly emphasized the importance of a federal law that protects confidentiality in the VA system of the RCA process. This law is the foundation for the non-punitive culture that characterizes the VA's efforts to learn from errors in order to improve patient safety. Mr. Anderson cited the law as 38 USC 5705, which can be found at the following link:

http://uscode.house.gov/uscodecgi/fastweb.exe?getdoc+uscview+t37t40+963+0++%28%29%20%20AND%20%28%2838%29%20ADJ%20USC%29%3ACITE%20AND%20%28USC%20w%2F10%20%285705%29%29%3ACITE%20%20%20%20%20%20%20%20%20

(A copy of the law has been printed and attached to the draft of the meeting minutes)

In addition to the points contained in the handouts that were provided, Mr. Anderson made the following points:

- When using RCA to determine "why" an adverse event or near miss occurred, investigators should avoid hindsight bias.
- Training RCA teams as needed is not difficult, and he spends about an hour getting a team ready to do their own investigations.
- If RCA indicates that there was an intentionally unsafe act committed, there are disciplinary procedures in place, and the confidentiality law doesn't prevent the VA from applying internal discipline.
- The VA requires RCA on near misses, as well as actual adverse events. Their philosophy is that a close call today is tomorrow's adverse event. RCA helps fill in any gaps that exist in protecting patient safety, including gaps that haven't actually resulted in an adverse event yet.
- The team of investigators that is assembled to conduct an analysis through RCA excludes people that may have been directly involved with an incident, but includes people from all different areas of operation, such as dietary, maintenance, management, etc. People directly involved are not on the team, but they are interviewed as part of the investigation.
- This helps the team maintain objectivity. The Rules of Causation (see handout) also help remove blame from the RCA process. An impartial team is one that does not gang up on an individual, or set one person out to gang up on another person.
- An action plan must assign specific people (not generic titles or areas) responsible for taking each action step. The Chief Executive Officer of the hospital signs off on the action plan recommended by the RCA team, or comes up with an alternative plan. The Action Plan is applied to the entire hospital.
- Thorough RCA attempts to ask and answer "why" at multiple layers and levels when determining the reason for an adverse event or near miss. The Office of the Inspector General scrutinizes the VA's action plans for thoroughness and timeliness of implementation.
- When implementing the RCA requirements, the VA experienced stiff resistance at first, due to a history of a culture of blaming, and also a perception of inconsistency. Another hurdle was the credibility of the people on the team when it came time to tell others to accomplish parts of the Action Plan recommendations. However, as more people have an opportunity to be involved on such teams themselves, they realize the thoroughness of the investigative process and tend to become active champions for RCA.

- The results of RCA analysis at every VA hospital are housed in a national databank. There are one hundred and fifty four (154) hospitals in the VA system that contribute data. The Truman Memorial VA does about thirty (30) RCA's a year. Smaller VA's do fewer. Smaller VA's are more likely to take advantage of outside consultants to help do an RCA.
- RCA teams often need coaching to really learn to dig into the "whys" and "so whats" of an incident. Teams are trained to start with the nine triage questions (see handout).

Discussion:
Is this process exclusive to the VA system?
No. Experts from the VA have trained personnel at other hospitals to do RCA like the VA.
The model is used widespread in the United States.
Kathryn Nelson agreed, and asked Mr. Anderson to provide some background information on Dr. Jim Bagain.
Dr. Bagain was a NASA astronaut and was the chief investigator of the Challenger disaster. He also aided in the investigation of the most recent space shuttle disaster. He is nationally and internationally recognized as a patient safety "guru".
What is the process for reporting near hits?
There are two. One is based on a NASA model with third party investigation. There is also a hotline system available to anyone – staff, patients and clinicians – through an 800 number and also on line (the Internet). Both systems are confidential and the hotline system is voluntary.
Some VA hospitals offer cash rewards for using the voluntary system, but the one in Columbia does not.
How do patients know about the hotline?
Through patient surveys and also the hotline number is posted all over the building. The NASA reporting form is also available.
Why doesn't the Columbia VA use a reward system for employees that voluntarily report incidents?
It's not necessary if people want to do the right thing.
Are there statistics on the number of close calls by category of root causes, like Training, Staffing, Failure to Follow Procedure, etc.?
Yes, from the national databank. Most of the VA hospitals are aging plants. The VA expects to see an increase in the number of root causes attributable to plant and equipment issues. The most common root cause is a breakdown in communication
How does the VA look at staffing and long work hours? Is a mandate to work not considered to be an intentionally unsafe act?
No. The system can be designed and built to support tired staff.
Does the federal privacy law mentioned earlier cover aggregated statistics?
Not sure. It wouldn't need to, because identifying information would not appear in statistical aggregates. There are no barriers to the information for persons inside the VA system, but the RCA data may not be available to the general public. One ongoing effect of the federal law is the continuing increase in the volume of voluntary reporting. At this point, it's not possible to say where this reporting is going to plateau.

How does one hospital's RCA results get communicated to the others?
All RCAs are reported to the VA's central database and all VA hospitals can query that database.
Does an action plan established by one VA hospital become national policy for the entire VA system?
Often yes. The VA has the power to direct system hospitals to adopt a best practice by a specific date. The VA also has the luxury of being able to see data, and how it should be applied, from a national system. One thing the VA has experienced is that a best practice designed to address one set of risks may be very successful, but may lead to a whole new set of risks developing. This has happened with bar coding all medications.
Has there been a chance to see if the whole system is adhering to best practices?
Yes.
What other policies besides bar coding medications have been nationalized due to the RCA at one hospital, and what follow-up investigating has been done to see if it's working as intended?
There have been many. There is measurable improvement system wide.
How well is this system deployed in Missouri?
It's wide spread, but not as thoroughly as in the VA system.
Should the Patient Safety Commission recommend the spread of this process to all Missouri hospitals?
Not without protection similar to that afforded to the VA hospitals under the protection of 38 USC 5705. RCA simply won't happen without comparable protection.

Nancy Kimmel noted that her hospital, Missouri Baptist Medical Center, debates the importance of involving individuals close to an incident on the actual RCA teams. Missouri Baptist Medical Center has found that having those directly involved serves as a vehicle for helping those people get past their own errors and failures, and prevents them from becoming the second victims of an incident. However, getting past the culture of blame is a huge issue. Mr. Anderson concurred, although the VA doesn't assign involved staff to the RCA, the involved staff is interviewed during the investigation process The debate is on a national level – MBMC has chosen to add the employee involved in the event because they are the second victim and it helps them with the understanding of the situation and be a part of the improvement process.

What about informing patients of an RCA and action plan? How is this done? How have patients responded? What effect has there been on the rate of litigation?
The VA mandates that patients be told if they were harmed. Ideally the patient is involved with the RCA. Patients are almost universally relieved and thankful to be told. Not sure exactly how informing patients has affected the VA hospital in Columbia, but some VA hospitals see a dramatic decrease, as much as 90%, in the pay-outs. The number of claims is unchanged system wide, but they are of lower value. The tort system used by the VA actually invites litigation, so the VA's experience can't be generalized to other hospitals.
So there is a court system available to VA patients, even with 38 USC 5705?
Yes.

General discussion on this point: If a VA patient takes a VA hospital to court, the federal court system is utilized. There is no jury. Judges set the award and tend to be more conservative than juries, but not always. State and VA laws on causes of action are not comparable. This makes it hard for non-VA hospitals to carry the RCA process too far, because people involved with the

incident will be told that the RCA process is discoverable. Convincing hospitals to adopt this process would be worthy, but very difficult without protection comparable to 38 USC 5705. Missouri, doesn't have comparable protection.

Stephen Smith proposed that the commission consider making a legislative recommendation modeled on 38 USC 5705. The commission generally agreed to give this proposal serious consideration.

Should the commission also recommend that patient safety concepts, including VA-style root cause analysis, be taught in medical and nursing schools?

Most commissioners agreed. No one objected to the idea.

What is the right number of RCA's per year, and what is the cost to conduct an RCA?

RCAs take an average of 18 hours to complete and involve 5 people in the VA system. So your cost is the cost of the man-hours. The VA system has national mandates for when RCA is necessary, but sometimes it's debatable what the value of the RCA is.

Is a remedy found in every case, or is there sometimes no root cause?

Often there is no root cause, especially in incidents related to suicides and patient wandering. However, RCA helps staff heal in these cases and affirms they are not at fault.

How do you apply RCA to a clinic or solo physician practice?

Frequent question. The Poplar Bluff VA hospital is a model for small organizations. They often take advantage of consultants from other VAs. Smaller hospitals could use a less complex model, but they also perform fewer RCAs per year.

Do RCAs and action plans ever involve supplies and equipment manufacturers?

Yes, but not as often as the VA would like. The VA has pressured suppliers from time to time to make specific changes.

Kathryn Nelson and Gregg Laiben thanked Mr. Anderson on behalf of the Commission.

III. MISSOURI BAPTIST MEDICAL CENTER

Nancy Kimmel, Patient Safety Specialist

Presented a PowerPoint on Creating a Culture of Patient Safety. (Handouts of the presentation are available)

Ms. Kimmel opened her presentation by asking Commissioners to give some thought about applying the process that Tim Anderson described, and the additional points she will be making, to non-hospital settings, such as doctor offices, ambulatory centers and clinics.

In addition to the information from her slides, Ms. Kimmel made the following points:

- Culture of the organization needs to be blameless but also hold people accountable for reckless acts. Missouri Baptist's leaders call this a "just" culture. It's important in doing RCA to separate the outcome from the event.
- "Silos" have been a problem in healthcare management for years, meaning people and functions from one clinical area do not communicate with or correspond to those in other clinical areas.

- **The commission should look at how organizations can apologize for mistakes that get made, without the apology being treated as an admission of guilt, and the regulatory boards need to look at developing a 'Just Culture' – accountability approach to reporting of errors. Systems review could get around regulatory discipline and individual blame.** MBMC does not routinely involve the patient in the RCA process – we do, however, involve the staff employee that was involved in the event.
- Missouri Baptist is involved with patient safety curriculum at the medical and nursing schools in and around St. Louis.
- Missouri Baptist has found that, in cases where errors are caused by persons taking a risk they didn't intend or weren't aware was risky, managing through education is often a two-way experience, in that management learns from front-line staff if a required procedure isn't feasible or actually causes problem. Education is done by learning which processes were faulty and those processes are owned by the management group – staff learn that by speaking up and reporting the faulty processes change will occur.
- In the hospital's experience, defenses that are built into the system to improve patient safety can still fail because the system is complex.
- Missouri Baptist provides feedback on reports of safety events, and also uses a monetary reward system, unlike the VA. Feedback is given through a newsletter that features a "We Heard You" item related to suggestions to improve patient safety.
- Failure Modes and Effects Analysis is an examination of systems before they fail, to isolate weak areas with latent failure that hasn't surfaced yet.
- There are currently 1,800 reports per month through the hospital's voluntary reporting system.

Discussion:

Is the newsletter with the "We Heard You" feature provided to patients?

Yes, in the form of a newsletter posted in the hospital.

When did Missouri Baptist launch its patient safety culture, and has the hospital seen less litigation since that point?

The culture initiative started in January 2000. Tracking of med mal or litigation claims, if it is done, would be processed by our Risk Management Dept – no info at the time of presentation on whether or not this is occurring.

Does Missouri Baptist disclose adverse events to patients?

Yes, but physicians are very fearful that an apology will be construed as an admission of guilt in court.

Have there been instances of liability based on disclosing adverse events to patients?

Not aware of any at the time of the presentation – MBMC does have ongoing communication with patient's and families before it would go to court.

How does Missouri Baptist decide the proper amount of money to offer a patient as compensation for an adverse event the hospital has disclosed?

An adverse event is disclosed immediately, before harm to the patient might be completely known. Compensation happens as the last phase of RCA, where action steps are assigned.

What stimulated Missouri Baptist to launch a patient safety culture?

The Institutes of Medicine Report in 1999 that publicized the volume of deaths due to medical error in hospitals.

What suggestions are there for getting other organizations to move to blame free or just cultures? The issue of protection has got to be addressed.
How much money is awarded to persons with good ideas for patient safety?
MBMC reviews suggestions for improving patient safety and awards $500 to $5000 based on the risk it reduces and the population that is affected.

Susan Kendig commented that there are a couple examples functioning inside the Department of Health and Senior Services where an adverse event triggers a panel review for non-punitive purposes. The panel examines systems that may have failed, thus leading to the adverse event, and makes recommendations to all Missouri hospitals in terms of its findings. This seems to intersect well with the presentations this morning, and perhaps these processes should go public.

The commission adjourned for lunch at 12:15 P.M. and reconvened at 1:10 P.M.

IV. STATISTICAL BREAKDOWN OF CLAIM & COMPLAINT DATA

Brent Kabler, Research Supervisor, Missouri Department of Insurance

Presented a PowerPoint on Cost Associated with Physicians with Multiple Claims. (Handouts of the presentation are available)

Dr. Kabler attempted to use medical malpractice claims data filed with the Missouri Department of Insurance to identify the costs associated with practitioners with multiple claims. In addition to the information on the handout, Dr. Kabler made the following points:

- Considerable manual editing was necessary for accuracy in provider names variances.
- The data presented today covers 1990 to 2002.
- The first two charts in the handout cover all providers while remaining charts address physicians and surgeons only.
- In general, the Missouri Department of Insurance data shows that a limited number of individuals are responsible for a disproportionate share of the costs.
- Injury severity codes are from the insurance industry. Most claims involve surgery. OB-Gyn is also frequently the subject of claims. Only a few practitioners in each hi-risk category tend to incur the claims.
- Insurers are reluctant and unprepared to offer premium discounts based on adoption of best practices. It's done in the workers' compensation industry if an employer has a "certified" safety procedure. Perhaps a similar model could be applied to the medical malpractice industry.
- The National Association of Insurance Commissioners established the injury severity code in the 1980s.

Discussion:
What is the definition of an "individual" as reported here?
If a person's name was associated with the claim, then that claim is for an individual. "All Providers" means physicians and surgeons plus every other claim.
Is this valid?
The definition is based on the insurance company's definition or identifier for a claim report. Insurers are supposed to identify if a practitioner or a hospital is involved in the claim, but they don't always do so.
So, the charts for "Physician and Surgeon" only includes a hospital based doctor if one happened To be named in the claim?
Correct.
Are high claims due to the risk of the area of specialty, such as surgery and OB-Gyn vs. dermatology, or due to the practitioner?
The data doesn't support a conclusion either way. But it should be noted that the majority of specialists in hi-risk areas such as surgery and OB-Gyn incur no claims.

The insurance industry has identified hi-risk specialties and sets premiums according to specialty. Is it bad public policy not to community rate hi-risk specialists?
The insurance industry cannot distinguish the portion of risk due to specialty area from the portion due to the person. A poor claims history will result in a person being rated higher than a person in the same specialty with no claim history. However, in other lines, such as auto insurance, claims history is known to be a poor predictor of future claims activity. Claims history may not be any better a predictor in the medical malpractice line.

Scott Lakin asked if the commission should consider whether or not the insurance industry should be required to community rate all doctors instead of segmenting doctors out into different groups based on specialty.

It is fascinating that three percent (3%) of doctors are responsible for twenty percent (20%) of the costs. Are these doctors who have skill or knowledge deficits, is it just bad luck, are they caring for exceptionally hi-risk patients, or are they just poor communicators? Can the Commission look at that? Do the Missouri Department of Insurance files allow categorization of each claim along the "just" model of the range of behaviors?
The files should contain information that allows the categorization of claims based on the type of behavior involved. That information can be presented to the Commission.

Deborah Jantsch commented that finding a reason for the premium increases is important, but that information should be de-identified. The Missouri Department of Insurance files might tell the commission about the acuity of the practice for doctors with multiple claims.
Did the insurance industry come up with the workers' compensation safety certification?
No. It was mandated for the Missouri Employers Mutual, the joint underwriting association established by statute. Other insurers copied the idea.
Deborah Jantsch commented that a premium discount of 5% or so doesn't help when premium increases have been in the range of 200%.

Does the type of act categorize the Missouri Department of Insurance data?
It will be going forward, but has not been up to now. The categories are based on those used for the National Practitioner Databank. It will be several years before sufficient data is collected under this system.
Can the data be analyzed to show the amount per claim for these categories?
Yes.
Is the Missouri Department of Insurance data for all cases, or for cases that are actually tried?
All cases. Only four percent (4%) of cases that go to the court system actually get tried.

Gregg Laiben recommended that a subcommittee may be named to look at this issue. One hundred and sixty eight (168) cases would be subjected to as close to an RCA as possible. Any state agency that has applicable data should be involved. The subcommittee will identify commonalities and apply a "just" behavior scale. Skill and knowledge deficits suggest a different course of action to correct than communication problems. Subcommittee members will be selected and asked to report at the next meeting with a plan for doing the work. Confidentiality and small sample sizes are an issue. The subcommittee will not try to identify people. Any commissioners willing to volunteer for this subcommittee should see Dr. Laiben or Linda Bohrer.

Barry Spoon suggested that the commissioners should look at a June, 2002 article in the Journal of the American Medical Association related to this issue. He will provide Linda Bohrer with a copy to disseminate to commissioners.

V. REGULATORY AGENCIES' COMPLAINT DATE

Lois Kollmeyer, Director, DHSS Section for health Standards and Licensure

Presented a PowerPoint on the Bureau of Health Facility Regulations (BHFR). (Handouts of the presentation are available)

- The presentation today addresses only some of the data collected by BHFR. BHFR lacks sufficient staff to assemble additional data in a timely manner.
- BHFR tracks complaints on the applicable regulation to which complaints pertain. **The commission may want to identify five to ten regulations that are related to near miss and actual adverse events for the next meeting.**

Discussion:
Are all complaints verified? Or are more complaints dealt with than are shown in the handout?
Yes. The complaint isn't counted unless it's substantiated by investigation. So, yes, BHFR handles more complaints than are shown in the official statistics.
Are hospitals required to report to BHFR if they have conducted their own internal investigation of an incident or near miss?
In a few specialized areas, but mostly no. However, many hospitals voluntarily report this information.
There is no way to know if a solution that works has been implemented?
Correct. If it's voluntarily reported, those that have fixed a problem are treated more leniently than those who haven't.

Several commissioners commented that it's a shame there isn't a way to disseminate successful solutions to all hospitals. Most hospitals will not be sophisticated enough, or have the resources, to do what the VA and Missouri Baptist have done.
Is this comparable to the petroleum industry, where the government helps fund clean up activities for companies that admit they found a problem, but imposes one hundred percent (100%) of the clean up costs on companies where the government goes in and finds a problem?
BHFR has no ability to impose fines, but doesn't ask for a Plan of Correction for problems that have already been corrected. BHFR can order a hospital to stop admitting patients if problems aren't fixed.
Who makes the complaints?
Mostly patients and families, but sometimes hospital management or hospital employees.
Can BHFR look at the complaint history for hospitals with known patient safety programs?
BHFR can look at this history, but doesn't see that there is much use in doing so. Patients are less likely to complain if the hospital voluntarily addressed any problems.
Is there a correlation between the severity of the complaint and the location of the hospital?
BHFR has not looked at that, although we can. However, Kansas City and St. Louis will stick out because those are the areas where the riskiest patients can go for necessary treatment.
Why are complaints up? Is it because of financial issues with the hospitals?
There are probably lots of reasons the number of complaints per year are rising. However, most complaints are due to inability to get information from the hospital.

Gregg Laiben commented that MissouriPRO sees similar issues with their complaints. Providers circle the wagons and patients get angry. Frequently, patient education on the normal risk of adverse outcomes and unpreventable problems doesn't happen.

Lori Scheidt, Executive Director, Missouri Board of Nursing

Presented a PowerPoint on statistical information. (Handouts of the presentation are available)
Linda Bohrer announced that she would e-mail the presentation to commissioners because of two slides being added.

- The Board of Nursing looks at all complaints and tries to perform RCA for each. Complaint investigations look at the systems in which the incident occurred.
- The Board of Nursing publishes a newsletter that provides information on any public disciplinary actions, and the names of the nurses involved.
- There is an article published that announces a pilot project in which the Boards of Nursing from several different states will collect and categorize complaint data using uniform "root cause" categories. Missouri is one of the pilot states.
- The Board of Nursing gets many "impaired provider" cases. Repeat complaints are most often in this category.

Discussion:
Regarding the disciplinary actions Censure and Flag, are those public?
Censures are public. Flags are not. A Flag is applied if the nurse involved can't be located and therefore an investigation can't be done. The flag allows the board to do the investigation if the nurse resurfaces.

Do "Letters of Concern" go into a nurse's permanent records with the Board of Nursing?
Yes. However, these are not public without a signed authorization from the nurse.
"Lack of attentiveness" is not a true root cause. Will Missouri's Board of Nursing push for identifying the true root cause of a complaint?
Yes. The article touches on this issue.
Do complaint investigations by the Board of Nursing ever result in changes mandated for the system in which the incident occurred?
Yes. The article explains this as well, but mandating a system change contributes to a punitive culture.
Regarding the identification of nurses subjected to disciplinary actions, and publishing this information in the newsletter, is this something that matters to the public? It's a punitive thing to do. Wouldn't it be better not to personally identify the nurses involved?

Several Commissioners responded to this question. State agencies have to balance the purely educational value of discussing problems without identifying disciplined persons, and the public's need to know about a bad actor. Agencies adhere to a significant due process before imposing any discipline. State agencies are perceived as accountable to the public, and the public expects disciplined actors to be identified. There is significant pressure from consumers and purchasers to identify disciplined hospitals and nurses. Finally, the Sunshine Law could be used to identify disciplined persons, even if the agencies didn't want to.
The morning's theme has involved making a distinction between persons who may commit normal human error and persons who deliberately act in an unsafe manner. What about persons that never get reported to the Board of Nursing?
The Board of Nursing typically only sees the very severe cases, and there are probably many more issues occurring than actually come to the attention of the Board of Nursing.
The Board of Nursing data doesn't support the idea that newer nurses are the biggest problems. Is this an indication that nursing education is sufficient?
It changes. Over a long enough period of time, the data would probably show swings. The Board of Nursing looks at the minimum education standards every few years.

Kevin Kinkade, Executive Director, Missouri Board of Pharmacy

Discussed the two handouts - "Board of Pharmacy Quality Assurance Program" and "Disciplinary Information – Complaints Filed".
In addition to the information on his handouts, Mr. Kinkade made the following points:
The Board of Pharmacy doesn't have sufficient staff to provide the Commission with the most up to date statistics, but will continue to work towards this goal.
The Board of Pharmacy licenses both facilities and individuals. Facility inspections and complaint investigations are both handled by the same staff of people.
The disciplinary process available to the Board of Pharmacy is similar to the processes at the Board of Nursing and the Board of Health Facility Regulation.
Discussion:
Is the Robert Courtney issue reflected in the Board of Pharmacy complaint data, and did it skew any of the information in this presentation?

Complaints filed with Board of Pharmacy regarding Dr. Courtney are included, but didn't have as much impact as one might expect
Are the problems with the State budget the source of Board of Pharmacy staffing issues? Is the Board of Pharmacy unable to perform its functions?
Yes and no. Funding for equipment is up. However, funding for staff has been slashed.
Regarding the slide with the pie chart, what is "Wrong Direct"?
This is a typo. The slide should read "Wrong Directions", meaning the directions for taking the medicine printed on the label are not the same as what the doctor wrote on the prescription.
So, of the sixty four percent (64%) of errors identified as "Wrong Directions", does the Board of Pharmacy give leeway for bad physician penmanship?
Sort of, but a pharmacist should clarify with the physician that wrote the prescription. True errors generally involve look-alike and sound-alike drug names.
How many pharmacists are licensed?
There are about 6,700 pharmacists and pharmacies that are licensed by the Missouri Board of Pharmacy, but only about 3,700 of those are actually practicing or operating in this State.
What was the range of disciplinary actions?
Twenty-six (26) probations, nine (9) suspensions, four (4) denials, six (6) revocations, and eight (8) restricted licenses issued.

Are pharmacy technicians licensed?
No. They are registered, but there is no license issued and no proof of competency is required. Only a criminal background check is required.
Do the technicians dispense and compound drugs? Isn't that a problem?
It depends. Each pharmacist and pharmacy makes a decision about what the technicians will be doing. However, the law places responsibility on the pharmacist or pharmacy for anything problematic that the technician does. The Board of Pharmacy hasn't observed a problem with proper oversight of pharmacy technicians. National data on this issue is limited. Missouri has no minimum ratio for the number of technicians per pharmacist.

The Commission stopped for a break at 2:40 PM and reconvened at 3:00 PM.

VI. MEDICAL MALPRACTICE LITGATION – CATEGORIES OF CASES

Thomas Cartmell, Senior Partner, Wagstaff & Cartmell, LLP
Kenneth Vuylsteke, Senior Partner, Fox & Vuylsteke, LLP

Mr. Cartmell began by making the following points:

(Nursing home data is not included in this study)

- Data from his firm is on currently pending cases.
- His firm is currently handling 242 cases, but these are allegations only and no determination of error has yet been made.
- The 242 cases involve 215 providers, so there are some providers with multiple cases pending.

- The data represents a good cross section of the universe of all litigation pending in Missouri because this firm is the biggest in Kansas City. It represents practitioners, large and small institutions, rural and urban. However, the firm does not generally handle pharmacists or pharmacies.
- Most cases are claims against physicians.
- Fifty percent (50%) of the cases are related to some kind of failure to diagnose a patient properly.
- Cases regarding foreign objects left in the body after surgeries never go away, although there are few currently pending.
- Cases regarding failure to get informed consent for a medical procedure are low because lawyers don't believe they can be won.
- Although data regarding nursing home cases isn't presented to the commission today because the attorney that handles these cases has been absent, those cases tend to fall under issues of nursing care and errors in administration of medications.
- **There is a great deal of litigation around outpatient settings, so looking outside the hospital to improve patient safety is critical.**
- Doctors aren't good at building in systematic double checks, such as assuring that a test that is ordered is actually carried out and the results are returned to the doctor's attention.

Discussion:
Are the cases involving failure to diagnose human failures or system failures?
This data doesn't say, and that's why it's not of very much value to the commission. Often cases involve failure to communicate between practitioners or at the point of transfer from one institution to another, or from an institution discharged to a doctor's care.
Is miscommunication happening before or after a failure to diagnose?
Both.

Several commissioners commented on the issue of communication breakdown. With regard to ensuring that doctors have double checks in their systems, it was suggested that insurers might be able to provide better incentives. Communication from one professional to another, versus communication between a professional and a patient is an important distinction to make. A communication breakdown is actually a system breakdown.
What systems ensure that hospital discharge information gets to the appropriate doctor's office?
The vast majority of doctors still rely on paper records. Electronic patient records typically are built to flag follow-up issues or alarming test results.

It was surprising that so many cases involved failure to diagnose, when the practice of defensive medicine is second nature to most physicians. How often in these cases is the doctor's judgment colored by outside pressure? Are these cases more affected by inappropriate patient expectations?
Outside agents can affect physician judgment in these cases. Often the doctor is identified as the one that failed to exercise medical judgment. However, that doesn't mean the standard of care was breached. The commission may not be able to change this apparent inconsistency. A similar inconsistency can be observed with surgical cases. **Often times bad outcomes are**

actually known risks. So the commission should be cautious because this data could be very misleading.
Isn't communication the key on those bad surgical outcome cases?
Sure. To backtrack, most cases are defensible, but not all. Some currently pending cases are egregious. There is tremendous pressure on reimbursement that has developed under managed care. Managed care leads to fewer defensive medicine practices and an increase in the volume of procedures that a doctor or hospital must perform. Physicians wind up spending less time on communication.

Kenneth Vulystke made the following points:

- Cases involving failure to properly diagnose can be attacked by looking at Diagnostic Related Groups and volume measures imposed by managed care. Doctors are pressured by their managed care contracts to diagnose in a manner that keeps expenses down.
- The cost and availability of tests is also an issue. Some physicians are reimbursed in a manner that requires the doctor to shoulder at least part of the cost of any diagnostic testing.
- Physicians let themselves be swayed by these financial pressures. Yet, there is no pending litigation against managed care companies. One managed care company uses a triage system based on a computer that saves only the first twenty-seven (27) characters of whatever the operator types into the system at the time. This is a calculated system designed to circumvent legal liability in pressuring doctors, because no litigation can go forward when there is no record of what happened.
- Informed consent cases are hard to win not because the providers do such a good job of assuring patients are informed, but because the legal bar is so high. **The Commission should not ignore informed consent and patient education issues, just because few such cases show up in the legal system.**
- **The Commission should eliminate categories of medical malpractice cases where nothing will help.**

Discussion:
What roll does lack of an electronic record play in litigation?

One commissioner felt that the problem with electronic information is that it's too easy to alter the record or destroy relevant information. Paper records are more difficult to convincingly manipulate. However, other commissioners felt that most electronic patient record systems have a "lock in" feature where previously entered information can be amended but not deleted. Most vendors have addressed protection.

Would it be safer to have a hand written record, because the physician would be more engaged?
Alan Morris responded by noting that his practice started using electronic records in 1985. The electronic records can be read. Electronic systems can be hacked as well as paper records. The cost barriers to implementing electronic systems is really the issue. Records from outside the doctor's office can be difficult to incorporate electronically. Therefore, lab results can still be missed, even when electronic systems are used. **The commission should look closely at the handling of information with regard to follow up care**

Isn't it true that the vast majority of medical malpractice never gets litigated because lawyers turn clients away if a case can't be won? Won't the recommendations of the Commission with regard to improving patient safety generally be of tremendous benefit to these people?
Agreed. There is a Harvard study that indicates only about one percent (1%) of medical malpractice is litigated.
Have Mr. Cartmell or Mr. Vulystke observed that juries are more inclined to be sympathetic in cases where there are tragic outcomes, even if there is no evidence of medical malpractice?
Yes. Managed care is again to blame. Juries are motivated by the suspicion that financial considerations swayed the physician to withhold care. But, juries also know there is a crisis in the medical malpractice market, and they don't wish to be part of the problem.
Yes. In addition to Mr. Vulystke's comments, physicians settle more frequently before getting to trial because of the hassle factor associated with defending themselves in court. Also, insurance companies don't like to hear that there's a low chance of winning a case. That attitude is probably having an effect on the Missouri Department of Insurance data.

Mr. Cartmell added that the data from his law firm highlights the problem medical providers have passing critical information from setting to setting. The commission should look at this. **In addition the issue of the impact of managed care on patient safety should be examined.**

James Buchanan commented that managed care has created issues with access to testing. He sees mostly Medicaid patients, which may or may not impact his perception, but he gets a lot of denials for tests with recommendations to refer patients elsewhere. So, HMO's <u>are</u> a patient safety issue.

James Utely commented in defense of managed care that expensive care doesn't always equate to safe care. Providers that aren't showing up in the legal system aren't getting paid any more for practicing safely than the providers who <u>do</u> show up in the legal system. Also, no one is lining up for higher health insurance premiums. While managed care is an easy target, it's not really the source of the problem.
Does the advertising by law firms create a safety issue because the ads are predatory and provide misinformation about drugs? To what extent do people deviate from their doctors' orders because they saw a misleading add for participation in a class action against a drug manufacturer?
The Missouri Bar is trying to mandate some fair marketing practices, but the advertising itself can't be stopped.
Could airing opposing ads neutralize the effect of these ads? Don't doctors know which patients are susceptible to this kind of advertising because of the medications the patients are known to be taking?
The danger in this strategy is that paternalistic doctors get sued for communicating ineffectively. While the data shows that some doctors get sued multiple times, what about the lousy doctors that don't get sued because they spend enough time with patients to fool patients into believing the doctor is doing a good job medically?
The American Orthopedic Society surveyed public perception of orthopedic doctors and found that orthopedic surgeons are perceived as "techies" with very poor communication skills. As a

result, the Society has begun to offer communication seminars. It's too soon to tell if these seminars will reduce litigation against orthopedic doctors.
Barry Spoon stated that he is aware of studies showing an instant reduction in litigation when physician communication skills are improved.
Does the Board of Healing Arts mandate communication training in the event a physician's license is disciplined?
Sometimes. Repeat offenders who don't rise to the level of actual discipline are encouraged to get training. If discipline is actually imposed, there are many continuing education requirements also imposed. Currently there is no state mechanism to require education in the absence of actual disciplinary action. The best situation would combine education and rehabilitation with keeping the physician in practice, although practice limitations might be appropriate in these circumstances.

Several commissioners agreed with this comment. **The commission should take a look at recommending legislative protection of the root cause analysis process.** There are instances where hospitals that shared information voluntarily with patients got sued anyway. So, it's not certain that improving patient safety and fostering an environment of shared information will reduce litigation, unless it also reduces incidents or protects the providers that share information.

The behavior of all types of practitioners involved in patient care might affect the patient's perception of attentiveness and adequate communication. **The commission should be cognizant of all the different types of practitioners that are involved**. **Any legislative protections should extend to all medical providers, not just hospitals and physicians.**
Nursing homes are a whole separate crisis in their own right. They rely very heavily on lower-level practitioners such as LPNs and nurse aides. If the commission intends to include the nursing home arena in its mission, then there needs to be an expert in nursing home issues brought to the commission.
Gregg Laiben invited Andrea Routh, former director of the Division of Senior Services, to provide some public comment on the commission's role with regard to the nursing home malpractice crisis. Ms. Routh, who was involved in the Governor's selection of commission members, commented that the size of the commission would have doubled if nursing home experts were also included. The commission's work may result in broadly applicable recommendations that will impact the nursing home situation. Or, **the Commission might consider recommending further investigation of the nursing home situation as a separate effort.**
Thomas Cartmell disagreed somewhat, and voiced the concern that going halfway towards addressing nursing home problems may just make problems worse. Scott Lakin agreed with Ms. Routh, stating that good ideas are likely to be co-opted by the nursing home industry, even if they weren't aimed in that direction.

Is the charge of the commission to both reduce medical malpractice claims and improve patient safety, or only to improve patient safety?
Patient safety only. Gregg Laiben agreed.

VII. ADDITIONAL RESEARCH NEEDS

What are the commission's recommendations to the Missouri Department of Insurance regarding the states that the commission would like more information from in regards to their patient safety efforts?

Alan Morris asked for more information about the recommendations that were made by the Illinois patient safety commission. They appeared more practical to him than the recommendations made in other states, such as Massachusetts.

William Schoenhard noted that he has been talking to the Missouri Hospital Association about how to approach the hospital associations of other states.

Kathryn Nelson, Vice-Chairperson

Suggested the commission pursue the following:

- Mandated versus voluntary reporting and protections
- Safety in the nuclear and aviation industries
- The efforts in the private sector with entities such as LeapFrog
- The work of Vanderbilt University on physician education
- Patient safety curriculum in medical and nursing schools
- Patient disclosure
- Technology innovations
- Patient and consumer education
- Alternative approaches to risk management and premium reductions

Presenters on each of these topics have been invited for the next few meetings. Presenters will ideally be scheduled around theme days, so that they will flow well from one to the next. There were no objections.

Gregg Laiben suggesting learning more about General Electric's "Break Through to Excellence" program. Because electronic patient record systems are not cheap, General Electric has rewarded physicians for making the capital investment necessary to move from paper to electronic records. General Electric is also offering incentives to patients to comply with medical advice.

VIII. PUBLIC COMMENT SEGMENT

The Chair called for any public comment. There was no public comment given.

IX. CLOSING COMMENTS

Gregg Laiben announced that Andrea Routh is leaving the Department of Insurance. He thanked her for her contributions to the commission and extended an invitation for her to attend future meetings.

X. MOTION TO ADJOURN

Thomas Cartmell made a motion to adjourn. The Chair approved the motion and the meeting was adjourned at 4:35 P.M.